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Attorneys for Dr. Caleb S. Hernandez

UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re: CERTA DOSE, INC., Debtor.	Case No. 21-11045-lgb Chapter 11

CERTIFICATE OF SERVICE

I, **ERIC S. MEDINA, ESQ.**, pursuant to 28 U.S.C. 1746, affirm as follows:

1. I am a member of MEDINA LAW FIRM LLC, counsel for Dr. Caleb S. Hernandez, D.O. ("Secured Lender") in the above-captioned matter. On April 5, 2022, true and correct copies of the following were served upon the persons and entities annexed hereto on the attached service list ("Service List"), in the manner so specified thereupon:

- Annexed certification of Dr. Caleb S. Hernandez, D.O.;
- April 5, 2022, Letter to Kenneth Silverman, Esq. as Chapter 11 Trustee enclosing credentials to documents and materials on www.box.com;
- Dr. Caleb Hernandez's Responses to subpoena dated March 15, 2022;

I declare under penalty of perjury that the information contained herein is true and correct to the best of my knowledge information and belief.

Dated: New York, New York
April 5, 2022

/s/ Eric S. Medina
Eric S. Medina, Esq.

SERVICE LIST

via Electronic Mail
Silverman Acampora, LLP
Chapter 11 Trustee Kenneth P. Silverman, Esq.
Brian Powers, Esq.
100 Jericho Quandrangle, Suite 300
Jericho, New York 11753

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Attorneys for Dr. Caleb Hernandez

UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re: CERTA DOSE, INC. Debtor.	Case No. 21-11045-lgb Chapter 11

CERTIFICATION AND DELCARATION OF DR. CALEB S. HERNANDEZ, D.O. MADE IN CONNECTION WITH RULE 2004 SUBPEONA DATED MARCH 15, 2022

I, **CALEB S. HERNANDEZ**, pursuant to 28 U.S.C. §1746 declare as follows:

1. I am a lender and the Chief Executive Officer ("CEO") of Certa Dose, Inc. ("Debtor" or "Certa Dose"). I make this declaration ("Declaration") in connection with my individual response to the subpoena issued by Kenneth Silverman, Esq. as chapter 11 trustee ("Trustee") of Certa Dose, Inc. ("Debtor" or "Certa Dose") dated March 15, 2022 ("Subpoena"). Unless otherwise stated, I have personal knowledge of the facts set forth herein and if required could and would testify competently hereto.

2. On March 23, 2022, I contacted Bridgehead I.T. ("Bridgehead") the vendor who provides information technology services to Certa Dose for the purpose of obtaining FDA compliant access to the information requested by the Trustee pursuant to the Subpoena.

3. I understand that compliant access could and was being granted to the Trustee by generating a username and password for the Trustee that enabled the Trustee to access the information sought by the Subpoena and to conduct "data mining" of the information sought by

the Trustee that is maintained by Certa Dose. Attached hereto as **Exhibit "A"** is a true and accurate copy of the email confirmation I received from Bridgehead following my request for the Trustee's access.

4. I was informed by the representative that credentials for the Trustee were modeled upon the user "Dan Hoffman" who enjoyed the highest level of access to Certa Dose systems, even greater than my own. I instructed that the username be created and have access to the data and that those credentials be transmitted to me so that they were transmitted to the Trustee. On March 24, 2022, the unique username and credentials for the Trustee were transmitted by my counsel to the Trustee. I further received a confirmation email that all of the files in the system and all access had been given to kenneth@certadose.com. The Trustee was given access to all of the corporate documents Certa Dose has in its system, over 2,685 documents. These files were made available to the Trustee, and I was made aware by the vendor that Mr. Nat Wasserstein had accessed the system, using this password, and was requesting assistance in navigating the system and finding documents. Since my transmittal on March 24, 2022, I understand there was and continues to be at least 2,685 documents and that at no time after transmittal did, I cause the data access provided to the Trustee to show that no documents were available or "nothing there."

5. In connection with the Subpoena, it has been asserted by the Trustee that I obstructively refused to provide passwords to accounts at Certa Dose to him. This is not true. First, I have stated in my response to the Trustee that, other than my own password, I do not have knowledge or access to the passwords of others users of Certa Dose systems. This is for the regulatory reasons that I discuss below.

6. I have directed my counsel to advise the Bankruptcy Court and the Trustee, as discussed on numerous occasions with Trustee's professionals, that unique usernames and

passwords including, data integrity, is critical to Certa Dose since it is regulated by the FDA and must conform to those rules. Failure to follow FDA rules has serious consequences including that violations result in Certa Dose products losing their FDA clearance to market and thus being deemed "adulterated" within the meaning of the Food Drug and Cosmetic Act, resulting in violations, statutory penalties, seizure and destruction of inventory, product recall and countless other penalties which I understand can include civil and even criminal penalties.

7. My counsel has indicated that as a result of a misunderstanding during the Bankruptcy Court proceedings on March 11, 2022, he failed to realize in his colloquy with the Bankruptcy Court that, rather than discuss FDA compliant access to systems, the word "password" was used to describe how information would be given to the Trustee. My counsel subsequently advised the Trustee of this error in responding to the Subpoena on March 24, 2022, and he subsequently transmitted a letter to the Bankruptcy Court dated March 30, 2022 [Doc. No. 256] to request a conference to further clarify the nature of the misunderstanding. Because Certa Dose operates in a highly regulated industry, it is not generally known or understood that a number of critical rules and practices must be adhered to in order to protect public health.

8. These regulations include 21 CFR Part 11 and Sharing Controls User Login Information. In order to enable the Bankruptcy Court and the Trustee to further understand the specific regulations and practices involved and why the turnover of my password or the use by others of common logon and passwords is a violation of FDA principles, I have commissioned an expert consultant on this topic. Annexed hereto as **Exhibit "B,"** is a true and accurate copy of the Quality Consulting Memorandum dated April 5, 2022 which discusses the FDA's regulations concerning FDA compliance.

9. In an abundance of caution and as result of the serious allegations made by the Trustee for which he has not provided any evidence, which for the avoidance of any doubt, I dispute I have reproduced at very significant expense to me personally a true and complete copy of each and every email maintained by me in connection with the operations of Certa Dose. Although I understand that the Trustee has access to the foregoing by virtue of the credentials that I provided to him, I have contemporaneously produced over 130,000 emails that were transmitted in the account caleb@certadose.com I have not in any manner, destroyed, concealed, or altered any such information (or any other information) in any manner. I have further produced an additional 300 emails bearing the email address drcaleb@certadose.com which was used by Certa Dose marketing professionals in connection with marketing materials. The Trustee has repeatedly stated that I am "giving him nothing,""not cooperating at all,"or variations on that accusation. To claim that I have given nothing is a bold claim, I respectfully seek that the Bankruptcy Court consider the evidence and communications I have caused to be set forth showing my repeated emails, documents and calls and meetings towards fulfilling all information requests to the Trustee.

10. In connection with the Subpoena, I have made a diligent search of all those records within my possession custody and control as set forth in connection.

Dated: New York, New York
April 5, 2022

By: /_____
Caleb S. Hernandez, D.O.

EXHIBIT “A”

Re: [EXTERNAL] Service ticket #1219527 - Need to add new user has been completed.

From: Bridgehead IT Support support@bridgehead-it.com
To: Caleb Hernandez Caleb@certadose.com
Date: Thu, Mar 24, 2022, 9:11 AM

--REPLY above this line to respond--

Bridgehead IT Service Ticket # 1219527/Need to add new user has been completed.

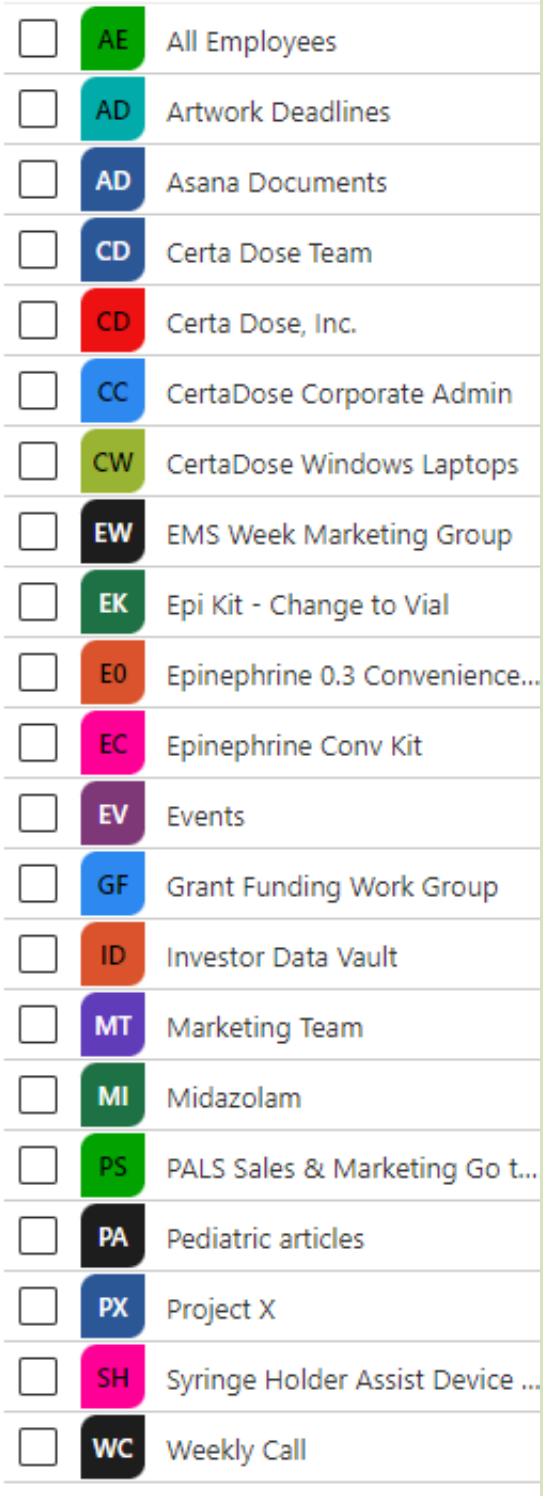
Ticket Summary:
Need to add new user

The resolution as documented by the technician is:

Thu 3/24/2022/8:00 AM UTC-05/ Erich Backhus (time)-

I performed the following:

- Added remaining groups to Kenneth's account
- Groups are as follows:



REMAINING ACTION ITEMS:

- No further action items at this time

Wed 3/23/2022/4:59 PM UTC-05/ Erich Backhus (time)-

I performed the following:

- Called and spoke to Caleb
- Model on Dan Hoffman
- Name: Kenneth Silverman
- Connected to AAD via Partner Portal
- Created Kenneth's AAD profile
- Assigned MS365 E3, EMS E3 and MS365 Audio Conferencing
- Unable to add to group All Employes due to service connection issues
- Will return to this section later
- Mailbox has provisioned
- Sent credentials to Caleb via encrypted email

REMAINING ACTION ITEMS:

- Assign to distro list All Employees

Wed 3/23/2022/4:58 PM UTC-05/ Vincent Rodriguez (time)-

Completed triage, escalation and ticket routing

Thank You,

Bridgehead I.T. Support Team

Wondering what to do next?

If there is additional work needed on this ticket there is still time to update your request in the Customer Service Portal or by replying to this email.

Bridgehead I.T. - 2810 North Flores, San Antonio, TX 78212 - (210) 477-7900

From: Caleb Hernandez Caleb@certadose.com
To: Bridgehead IT Support support@bridgehead-it.com
Date: Thu, Mar 24, 2022, 8:06 PM

Caleb Hernandez, DO, FACEP
President & CEO
Certa Dose, Inc.

Mobile: 347.866.7657
caleb@certadose.com
www.certadose.com

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2 Emails

EXHIBIT “B”

QA CONSULTING

MEMORANDUM

To: Caleb Hernandez, President and CEO, Certa Dose, Inc.

From: Amber Hilfiger, Director of Operations and Sr. Quality Engineering Consultant, QA Consulting, Inc.

Date: 05 April 2022

Subject: Opinion on Compliance with 21 CFR Part 11 and Sharing Controls User Login Information

Purpose

The purpose of this memo is to assess 21 CFR Part 11 as it pertains to controls regarding authorization for individuals who may "create, modify, maintain, or transmit electronic records"[1] and who may use electronic signatures. The analysis is intended to evaluate what the requirements are for individual authorization methods such as identification codes and passwords and if the regulation allows for sharing of user identification codes and passwords (user login information) by multiple users.

Analysis

21 CFR Part 11 is the regulation that defines the requirements for electronic records and electronic signatures to be handled such that they are considered to be "trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper."[2] The regulation is intended to ensure the "authenticity, integrity, and confidentiality"[3] of electronic records and electronic signatures. Medical device manufacturers who are registered and listed to market medical devices within the US are required to comply with 21 CFR Part 11. Application of this regulation also applies to medical device manufacturers as they are developing a medical device that will be intended to market within the US.

For electronic records (21 CFR Part 11 Subpart B), system access must be limited to authorized individuals[4] and secure, computer-generated, time stamped audit trails must exist to independently record the date and time of operator entries and actions to electronic records.[5] Sharing of user login information would prohibit the ability to clearly delineate the identity of authorized users/operators taking action on an electronic record.

For electronic records (21 CFR Part 11 Subpart C), a key element of the regulation is the *uniqueness* of user login information. "Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else."[6] Furthermore, an entire section of the regulation, 21 CFR Part 11.300 covers the requirements for identification codes/passwords (user login information) for electronic signatures. This section includes the following statements, which all indicate that controls required for user login information do not permit the sharing of such information across multiple individuals:

[1] 21 CFR Part 11 Section 11.10
[2] 21 CFR Part 11 Section 11.1(a)
[3] 21 CFR Part 11 Sections 11.10 and 11.30
[4] 21 CFR Part 11 Section 11.10(d)
[5] 21 CFR Part 11 Section 11.10(e)
[6] 21 CFR Part 11 Section 11.100(a)

- "Persons who use electronic signatures based upon use of identification codes in combination with passwrods shall employ controls to ensure their security and integrity;"[7]
- "Maintaining the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identifcation code and password."[8]
- "Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and to detect and report in an immediate and urgent manner any attempts at their unauthorized use to the system security unit, and, as appropriate, to organizational management."[9]

Conclusion

Based on the analysis above, it is my opinion that sharing of user login information for any software or platforms used to manage electronic records and/or electronic signatures does not comply with 21 CFR Part 11. These software systems and platforms that may be used by medical device manufacturers include eQMS software (such as Greenlight Guru, Qualio, Grand Avenue Software, etc.); Sharepoint, signature programs (such as AdobeSign or DocuSign), and emails.

Approvals:

Amber Hilfiger, Director of Operations

05 Apr 2022
Date

[7] 21 CFR Part 11 Section 11.300
[8] 21 CFR Part 11 Section 11.300(a)
[9] 21 CFR Part 11 Section 11.300(d)